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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,402	09/17/2001	Julio Cesar Aguilar Rubido	976-11 PCT/US	3056

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08/24/2006

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EXAMINER

SALVOZA, M FRANCO G

ART UNIT PAPER NUMBER

1648

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/857,402

Applicant(s)

AGUILAR RUBIDO ET AL.

Examiner

M. Franco Salvoza

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15,16,21-23 and 38-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15,16,21-23 and 38-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 17, 18, 25-27 have been canceled. Claim 38 has been amended.

Claims 15, 16, 21-23, 38-42 are pending and under consideration.

Claim Rejections - 35 USC § 103

WITHDRAWN

Claim 15 was rejected under 35 U.S.C. 103(a) as being unpatentable over Wands et al.

Applicant submits that the presentation of unfused HBsAg and HCV core antigens is not necessarily equivalent to the presentation of the antigens in a fusion protein; antigens in a fusion protein are attached to each other, and if the antigens are unfused, the unfused antigens may not contact the same cell.

Applicant's arguments are considered and found persuasive. The rejection is withdrawn.

Claim Rejections - 35 USC § 102

MAINTAINED

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15, 16, 21-23 were rejected under 102(b) as being anticipated by Tabor et al. in light of Bowen et al.

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Applicant submits that there is no disclosure or suggestion in Tabor et al. of a formulation for mucosal administration having HBsAg antigen and a viral nucleocapsid or virus-like particle, and further that the HBsAg has an adjuvant effect on the viral nucleocapsid or virus-like particle.

Applicant's arguments are considered but ^{not} found persuasive.

As indicated in the previous Office Action, the adjuvant effect is an inherent functional limitation conferred by the structure of the claimed invention, namely, the vaccine composition comprising a mixture of a first vaccine antigen which is HBsAg and a second vaccine antigen which is a viral nucleocapsid or a virus-like particle.

Additionally, the recitation of the formulation suitable for mucosal administration is a statement of intended use. Thus, in light of the teachings of Bowen et al., the rejection stands on that basis alone.

The rejection is maintained for reasons of record.

Claim Rejections - 35 USC § 103

MAINTAINED

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 38-41 were rejected under 103(a) as being unpatentable over Tabor et al. in light of Bowen et al. and further in view of Rose et al. and Hauser et al.

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Applicant submits that there is no disclosure of the formulation for mucosal administration and there is no disclosure or suggestion that the HBsAg has an adjuvant effect on the second or third vaccine antigen.

As indicated in the previous Office Action, the adjuvant effect is an inherent functional limitation conferred by the structure of the claimed invention, namely, the vaccine composition comprising a mixture of a first vaccine antigen which is HBsAg and second vaccine antigen and a third vaccine antigen.

Additionally, the recitation of the formulation suitable for mucosal administration is a statement of intended use.

The rejection is maintained for reasons of record.

Claim 42 was rejected under 35 U.S.C. 103(a) as being unpatentable over Tabor et al. in view of McCluskie et al.

Applicant submits that McCluskie et al. neither discloses nor suggests that a vaccine that can be administered parenterally can necessarily also be effectively administered mucosally, and further, that delivery by the mucosal route will induce an immune response.

Applicant's arguments are considered and found unpersuasive.

As indicated previously, the recitation to the composition suitable for mucosal administration is interpreted as a statement of intended use.

However, McCluskie et al. was not cited to suggest that any composition that can be administered parenterally can necessarily also be effectively administered mucosally, but merely as further support of that mucosal administration of a composition induces an immune response,

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as demonstrated by McCluskie, teaching vaccine administration over the nares of mice and subsequent immune responses elicited therefrom (p. 247).

Carrano et al. (U.S. Patent 5, 962, 468, issued Oct. 1999) is cited merely in support of the rejection of Tabor et al. in view of McCluskie et al. to demonstrate that HBV antigens can be administered either parenterally or mucosally. Carrano et al. teaches vaccine compositions comprising gene constructs containing HBV structural genes encoding surface antigens and/or core antigens and/or precore antigens (Examples 47, 48). Carrano et al. also teaches that the compositions can be delivered through a variety of routes, including mucosal and parenteral:

According to the invention, the gene constructs may be administered directly into the individual to be immunized or ex vivo into removed cells of the individual which are reimplanted after administration. By either route, the genetic material is introduced into cells which are present in the body of the individual. Routes of administration include, but are not limited to, intramuscular, intraperitoneal, intradermal, subcutaneous, intravenous, intraarterially, intraocularly and oral as well as transdermally or by inhalation or suppository. Preferred routes of administration include intramuscular, intraperitoneal, intradermal and subcutaneous injection. Delivery of gene constructs which encode target proteins can confer mucosal immunity in individuals immunized by a mode of administration in which the material is presented in tissues associated with mucosal immunity. Thus, in some examples, the gene construct is delivered by administration in the buccal cavity within the mouth of an individual. (column 13)

The rejection is maintained for reasons of record.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period


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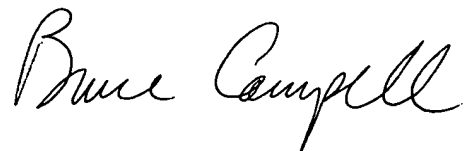
will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Franco Salvoza whose telephone number is (571) 272-8410. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


M. Franco Salvoza
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